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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/023,232	02/13/1998	ANN MONOSOV	312762001530	6662

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/023,232	Applicant(s) MONOSOV ET AL.	
	Examiner Anne Marie S. Wehbe	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20-25, 27, 28, 30-37, 42-49 and 54-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 8-13, 15, 17, 20, 22, 24, 27-28, 30, 33-34, 37, 42, 45-46, 49, 54, 57-58, and 61 is/are rejected.
- 7) ☒ Claim(s) 3-7, 14, 16, 18, 21, 23, 25, 31, 32, 35, 36, 43, 44, 47, 48, 55, 56, 59 and 60 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this reissue application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/2/04 has been entered. Applicant's amendments, arguments, and declaratory evidence as submitted on 1/2/04 have been entered as well. Claims 1-18, 20-25, 27-28, 30-37, 42-49, and 54-61 are currently pending in the instant application. An action on the merits follows.

Claim Rejections - 35 USC § 103

The rejection of claims 1-13, 15, 17-18, 20, 22, 24, 27-28, 30-37, 42-49, and 54-61 under 35 U.S.C. 103(a) as being unpatentable over Kyriazis et al. (1981) Canc. Res., Vol. 41, 3995-4000 in view of Otto et al. (1985) J. Urol., Vol. 134, 170-174, Wang et al. (1982) Exp. Cell. Biol., Vol. 50, 330-331, and McLemore et al. (1987) Cancer Research, Vol. 47(19), 5132-5140, is withdrawn in view of applicant's amendments to the claims, arguments, and the second declaration by Robert M. Hoffman and accompanying exhibits. The claims have been amended to clearly indicate that transplanted tumor tissue both grows at the primary site and metastasizes to secondary sites so as to mimic the progression of both the primary tumor growth and the

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metastatic behavior of the tumor in humans. Applicant's arguments regarding "unexpected results" in generating patterns of metastasis in Metamouse which faithfully mimic those observed in humans have been found persuasive in overcoming the rejection of record over the claims as amended based on the comparison of metastases observed by Kyriazis et al. and Otto et al. and those obtained using MetaMouse provided as exhibit 2 (exhibit A) of the Hoffman declarations, and the newly provided relevant sections of Holland et al., Cancer Medicine, published in 1973, and the updated edition published in 2000, which teach the expected pattern of metastasis for various tumors in humans.

The rejection of claims 14, 16, 21, and 23 under 35 U.S.C. 103(a) as being unpatentable over Kyriazis et al. (1981) Canc. Res., Vol. 41, 3995-4000 in view of Otto et al. (1985) J. Urol., Vol. 134, 170-174, Wang et al. (1982) Exp. Cell. Biol., Vol. 50, 330-331, and McLemore et al. (1987) Cancer Research, Vol. 47(19), 5132-5140 as applied to claims 1-13, 15, 17-18, 20, 22, 24, 27-28, 30-37, 42-49, and 54-61 above, and further in view of Giovanella et al. (1984) Exp. Cell. Biol., Vol. 52, 76-79, is withdrawn in view of applicant's amendments to the claims, arguments, and the second declaration by Robert M. Hoffman and accompanying exhibits. Please see the examiner's comments above.

The rejection of claims 18 and 25 under 35 U.S.C. 103(a) as being unpatentable over Kyriazis et al. (1981) Canc. Res., Vol. 41, 3995-4000 in view of Otto et al. (1985) J. Urol., Vol. 134, 170-174, Wang et al. (1982) Exp. Cell. Biol., Vol. 50, 330-331, and McLemore et al. (1987) Cancer Research, Vol. 47(19), 5132-5140 as applied to claims 1-13, 15, 17-18, 20, 22, 24,

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27-28, 30-37, 42-49, and 54-61 above, and further in view of Reddy et al. (1987) Cancer Res., Vol. 47 (9), 2456-2460, is withdrawn in view of applicant's amendments to the claims, arguments, and the second declaration by Robert M. Hoffman and accompanying exhibits. Please see the examiner's comments above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 8-13, 15, 17, 20, 22, 24, 27-28, 30, 33-34, 37, 42, 45-46, 49, 54, 57-58, and 61 are newly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 5,491,284 (2/13/96), hereafter referred to as the '284 patent. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons. The instant claims and claims 1-21 of the '284 patent both recite methods of generating mouse models of metastases comprising transplanting histologically intact human neoplastic tissue onto an organ of a nude mouse which corresponds

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to the human organ from which said tissue is originally obtained and allowing the transplanted tissue to grow and mimic the progression of neoplastic disease in the human. The claims of the '284 patent, however, are narrower than the instant claims. Claims 1-21 are specifically limited to nude mice, and to human neoplastic tissue selected from the stomach, colon, pancreatic or lung tissue. The instant claims are broader in that they are not limited to human neoplastic tissue selected from the stomach, colon, pancreatic or lung tissue, but read on any human neoplastic tissue. Further, while instant claims 1-2, 8-12 are limited to nude mice, claims 13, 15, 17, 20, 22, 24, 27-28, 30, 33-34, 37, 42, 45-46, 49, 54, 57-58, and 61 read on nude rodents or immunodeficient rodents. It is well established that a species of a claimed invention renders the genus obvious. *In re Schaumann*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978). Therefore, as a species of the broader instant claims, claims 1-21 of the '284 patent render the instant claims obvious.

Please note that the office acknowledges that a terminal disclaimer over US Patent No. 5,491,284 was submitted in US Patent application no. 08/459,730, which issued as US Patent No. 5,569,812, which is the basis for this reissue application. However, since the instant application is separate from the 08/459,730 application, a new terminal disclaimer is required.

Claims 3-7, 14, 16, 18, 21, 23, 25, 31-32, 35-36, 43-44, 47-48, 55-56, and 59-60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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The applicant is reminded that the original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178..

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. For all official communications, the technology center fax number is (703) 872-9306. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

